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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,635	09/22/2003	Stephen E. Barry	ALNS-006P3	1104

23979 7590 11/04/2005

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EXAMINER	
DO, PENSEE T	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,635	BARRY ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/22/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SDU

DETAILED ACTION

Specification

The disclosure is objected to because it contains an embedded hyperlink on page 12 and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 8, 12, 16, 24, 25, 28 and 29 of U.S. Patent No. 6,844,842 in view of Klaus (Trends in Biochem. Sci., 19(9) January 1994, pp 9-14).

Patent '842 claims a synthetic polymer (comprising of amphiphilic monomers equivalent to hydrophilic) complement (SPC) comprising a crosslinked three-dimensional polymeric network having a diameter less than about 1000 nm and

comprising a target binding sites, which comprises three-dimensional cavities (3-D binding sites), complementary to at least a portion of the surface of the target; and a head group selected from the group consisting of sugars such as glucose-2-acrylamide (saccharide), proteins, carbohydrates, which head group is a functional group capable of undergoing a binding interaction with the site of the target and a crosslinking group. The polymeric network further comprises of monomers consisting of a crosslinking group without a head group (scaffolding building blocks). According to the specification of the present invention, "Scaffolding building blocks" are defined as building blocks other than the high affinity building blocks comprising of crosslinking groups. Thus, the monomers without the head group (high affinity molecules) are equivalent to the scaffolding building blocks of the present invention. The target is selected from the group consisting of organic compounds, proteins, nucleic acids, etc. (clm. 5).

However, Patent '842 fails to recite that the binding interaction between head group with the target is non-covalent and that the high affinity molecules are amino acids or nucleic acids.

Klaus discusses different approaches of molecular imprinting and one of those approaches allows a cocktail of functionalized monomers to prearrange around the imprint molecules (target template) by nonconvalent interactions (i.e. ionic, hydrophobic, hydrogen bonding, etc). After completion of polymerization, the imprint molecule is removed from the polymer, leaving a polymer with recognition sites complementary to the imprint species in both shape and functionality, which has a macroporous structure allowing imprint (target) molecule diffusion into and out of the polymer matrix (polymeric

network). This approach is a simple and straightforward method for preparing synthetic polymers of predetermined selectivity. (see p. 9, col. 2).

It is well known in the art, according to the discussion of Klaus, that interaction between the head group or functionalized monomers and the binding site on the target is a non-covalent interaction and thus would have been obvious to one of ordinary skills in the art to use such non-covalent interaction as discussed in Klaus to synthesize the polymeric complement of Patent '842 and would have a reasonable expectation of success since both patent '842 and Klaus teach the same molecular imprinting technique. Furthermore, such non-covalent interaction between the target and the head group of the polymeric network enables the recycling of the polymeric network since non-covalent interaction is weak interaction and reversible. Regarding claims 13 and 14, since Patent '842 recites that the target can be nucleic acids, it would have been obvious to one of ordinary skills in the art to have a functionalized monomer or head group complementary to the target molecule and it is known in the art that complementary molecules to nucleic acids are nucleic acids that can form complementary strand to the target nucleic acid and nucleic acids are amino acids. Therefore, Patent '842 meets the requirements of claims 13 and 14.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 1-16 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

The claimed subject matter has been patented in Patent 6,884,842. The inventors of Patent 6,884,842 are Soane, Barry, Goodwin, Offord and Perrott. However, the present application lists only Soane and Barry as inventors. Assignee requires to name first inventor of conflicting subject matter or show inventions were commonly owned at the time of Applicants' invention.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6-9, 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Arnold et al. (US 5,310,648).

Arnold teaches a fluid imprinted matrix which exhibits selective binding interactions through metal chelates or interactive moieties with a predetermined molecule or biological particle. A polymerizable lipid monolayer, membrane or vesicles are examples of preformed fluid imprint matrices. Polymerizable membranes are formed from amphiphilic lipid monomers that contain a lipid tail and a hydrophilic head group. Some fractions of these monomers (high affinity blocks) contain interactive moieties (high affinity molecules) attached to the head group. These monomers are free to diffuse laterally within the membrane prior to polymerization. Such diffusion allows imprinted matrices to be made without the use of chelated metals for specific interactions. Such interactions can be hydrogen bonds, hydrophobic interactions, van der Waals forces, etc. (non-covalent binding) between an interactive moiety on the

membrane surface and binding sites on the print substrate (target). Therefore interactive moiety refers to a chemical group capable of binding a template molecule through hydrogen bonds, hydrophobic interactions, and etc. through metal coordination. The interactive moieties can be the head groups of the lipids or moieties specifically attached to the head groups, which will have affinity for binding sites on the print substrate. Functional groups possessing positive or negative charges are examples of interactive moieties. (See col. 7, lines 25-55). Regarding the three-dimensional binding sites, since Arnold teaches that the binding sites can non-covalently bind to the target or are complementary to the target and that the template which is complementary in shape is imprinted on the substrate, it is inherent that such binding sites are three-dimensional because for the substrate to have a complementary shape which constitutes a three-dimensional figure, the binding sites on the template and the substrate must be three dimension for such substrate to have an imprint of the template material. For claim 2, the interactive moieties of Arnold are equivalent to the active agents of the present invention. Regarding claims 6, since Arnold teaches that the interactive molecules are attached to the binding site surrounded by monomers, it is inherent that the position of those moieties in said binding site is stabilized by a polymer network because the monomers are polymerizable. Regarding the Scaffolding building blocks, since Arnold teaches that "some fractions of the monomers contain interactive moieties (high affinity molecules)", it is inherent that the other fraction of the monomers lack interactive moieties and these monomers meet the requirement of the scaffold building blocks of the present invention for the specification of the present invention describes that

"scaffold building blocks are building blocks other than high affinity building blocks". Arnold also teaches that the imprinted matrix comprises of cross-linking agents (see col. 3, lines 30-54).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,844,842 in view of Klaus (Trends in Biochem. Sci., 19(9) January 1994, pp 9-14).

The applied reference has a common ***inventor*** with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the

application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Patent '842 claims a synthetic polymer (comprising of amphiphilic monomers equivalent to hydrophilic) complement (SPC) comprising a crosslinked three-dimensional polymeric network having a diameter less than about 1000 nm and comprising a target binding sites, which comprises three-dimensional cavities (3-D binding sites), complementary to at least a portion of the surface of the target; and a head group selected from the group consisting of sugars such as glucose-2-acrylamide (saccharide), proteins, carbohydrates, which head group is a functional group capable of undergoing a binding interaction with the site of the target and a crosslinking group. The polymeric network further comprises of monomers consisting of a crosslinking group without a head group (scaffolding building blocks). According to the specification of the present invention, "Scaffolding building blocks" are defined as building blocks other than the high affinity building blocks comprising of crosslinking groups. Thus, the monomers without the head group (high affinity molecules) are equivalent to the scaffolding building blocks of the present invention. The target is selected from the group consisting of organic compounds, proteins, nucleic acids, etc. (clm. 5).

However, Patent '842 fails to recite that the binding interaction between head group with the target is non-covalent and that the high affinity molecules are amino acids or nucleic acids.

Klaus discusses different approaches of molecular imprinting and one of those approaches allows a cocktail of functionalized monomers to prearrange around the imprint molecules (target template) by nonconvalent interactions (i.e. ionic, hydrophobic, hydrogen bonding, etc). After completion of polymerization, the imprint molecule is removed from the polymer, leaving a polymer with recognition sites complementary to the imprint species in both shape and functionality, which has a macroporous structure allowing imprint (target) molecule diffusion into and out of the polymer matrix (polymeric network). This approach is a simple and straightforward method for preparing synthetic polymers of predetermined selectivity. (see p. 9, col. 2).

It is well known in the art, according to the discussion of Klaus, that interaction between the head group or functionalized monomers and the binding site on the target is a non-covalent interaction and thus would have been obvious to one of ordinary skills in the art to use such non-covalent interaction as discussed in Klaus to synthesize the polymeric complement of Patent '842 and would have a reasonable expectation of success since both patent '842 and Klaus teach the same molecular imprinting technique. Furthermore, such non-covalent interaction between the target and the head group of the polymeric network enables the recycling of the polymeric network since non-covalent interaction is weak interaction and reversible. Regarding claims 13 and 14, since Patent '842 recites that the target can be nucleic acids, it would have been obvious to one of ordinary skills in the art to have a functionalized monomer or head group complementary to the target molecule and it is known in the art that complementary molecules to nucleic acids are nucleic acids that can form

complementary strand to the target nucleic acid and nucleic acids are amino acids. Therefore, Patent '842 meets the requirements of claims 13 and 14.

Claims 3-5, 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arnold (US 5,310,648) in view of Stainmesse et al. (US 5,133,908).

Arnold have been discussed above.

However, Arnold fails to teach specific size of the nanoparticle.

Stainmesse teaches a process for preparation of dispersible colloidal nanoparticles. Stainmesse also teaches that nanoparticles with diameter less than 500 um is known. (see col. 1, lines 15-16). Stainmesse also teaches preparing a colloidal system of a protein in the form of spherical particles of the matrix type and of a size of less than 500 nm. (se col. 10, lines 42-45).

It would have been obvious to one of ordinary skills in the art to use nanoparticles with diameter less than 500 nm as taught by Stainmesse as a matrix in the method of Arnold because both references teach the concept of using nanoparticles as matrix coupled to a protein. Small size nanoparticles are known to have long term stability and homogenous in suspension. (see col. 2, lines 10-18).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
September 20, 2005

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10/03/05